

20. (New) A multi-component sealant applicator comprising:

an inner catheter positioned coaxially within an outer catheter, the inner and outer catheters each configured for delivering one or more sealant components; and

35 a mixing volume at a distal end of the inner and outer catheters for mixing the one or more sealant components prior to discharge from the distal end of the inner and outer catheters.

21. (New) A multi-component sealant applicator comprising:

an inner catheter defining a first area, the inner catheter configured for delivering one or more sealant components;

an outer catheter defining a second area, the second area capable of receiving the first catheter therein and configured for delivering one or more sealant components;

a mixing volume at a distal end of the inner and outer catheters for mixing the one or more sealant components prior to discharge from the distal end of the inner and outer catheters.

REMARKS

Claims 1-19 of the present application are currently pending. Claims 1-5, 7, 11, 15, 16, and 19 have been rejected and claims 8, 12-14, and 17 have been withdrawn from consideration pursuant to 37 CFR 1.142(b) as being drawn to a non-elected species. The Applicants respectfully submit the withdrawal of claims 8, 12-14, and 17 is without prejudice.

In the Office Action dated August 8, 2002, the Examiner rejected claims 1-4, 7, 16, and 19 under 35 U.S.C. §102(b), and claims 5, 11, and 15 under the provisions of 35 U.S.C. §103(a). In addition, claims 6, 9, 10, and 18 were objected to as being dependent on a rejected base claim, but would be allowable if re-written in independent form to include the limitations of the base claim and any intervening claims.

In response, each one of the cited references has been reviewed and the rejections and objections made to the claims by the Examiner have been considered. Claims 1 and 19 have been amended to more clearly recite the novel features of the

presently claimed invention, claims 6, 9, 10, and 18 have been re-written in independent form to include all the limitations of the base claim and any intervening claims, and independent claims 20 and 21 were added.

For the reasons set forth below, it is submitted that all the pending claims are in condition for allowance and allowance of the application is respectfully requested.

Rejections under 35 USC §102

In the Office Action dated August 8, 2002, independent claim 1 and dependent claims 3, 4, and 16 were rejected under 35 USC §102(b) as being anticipated by United States Pat. No. 4,935,006, issued to Hasson. (hereinafter *Hasson '006*), independent claim 1 was rejected under 35 USC §102(b) as being anticipated by United States Pat. No. 4,601,697, issued to Mammolenti et al. (hereinafter *Mammolenti '697*), and independent claim 1 and dependent claims 2, 7, and 19 were rejected under 35 USC §102(b) as being anticipated by United States Pat. No. 4,631,055, issued to Redl et al. (hereinafter *Redl '055*). For the reasons set forth below, the Applicants respectfully traverse the rejections and respectfully submit that the pending claims define patentable subject matter over the cited prior art.

Claim 1 of the presently claimed invention is directed to an improved component mixing catheter and includes a dual catheter for delivering sealant, and a mixing volume at the distal end of the dual catheter for mixing components of a multi-component sealant prior to discharge from the distal end of the catheter. Claim 19 of the presently claimed invention is directed to a method of applying a multi-component sealant to anatomical surfaces, and includes flowing multiple sealant components through a longitudinally compartmented catheter, and mixing the components within a distal end of the catheter immediately prior to discharge.

The Hasson '006 reference

Claims 1, 3, 4, and 16 were rejected as being anticipated by the *Hasson '006* reference. The *Hasson '006* reference pertains to a suction and irrigation device with a right angle and oblique openings, and includes a first tube connectable at its proximate end to a vacuum source and open at its distal end to provide suction to the distal end, a second tube having a lengthwise axis disposed around the first tube to define an outer channel therebetween, and a device for discharging fluid irrigation from the outer

channel at the distal end of the device. The distal end of the device may include a plurality of openings extending obliquely through the second tube, the openings being arranged in annular arrays and positioned to permit a random fluid discharge that showers the area around the second tube. During use, the user may operate a valve 40 to dispense an irrigating fluid from the *Hasson '006* device. In addition, the user may actuate another valve 18 to apply a vacuum force to the tissue proximate to the distal end of the *Hasson '006* device. However, unlike the presently claimed invention which mixes two fluid sealant components within the distal end of the catheter prior to dispensing the material, the *Hasson '006* device fails to mix any fluids within the distal end of the device prior to discharge.

For at least the reasons stated above, it is respectfully submitted that independent claim 1 is not anticipated by the *Hasson '006* reference. Moreover, for at least the same reasons, it is submitted that dependent claims 3-4, and 16 are also patentable.

The Mammolenti '697 reference

Claim 1 was rejected as being anticipated by the *Mammolenti '697* reference. The *Mammolenti '697* reference pertains to a long dwelling side-by-side double bore catheter for the dilution and sampling of body fluid, the double bore body having flush distal ends and a mixing chamber located at the flush distal ends. The mixing chamber includes a non-circular opening which communicates with the body fluid. During use, a diluent is advanced through the first bore to the mixing chamber and mixed with body fluid located within the mixing chamber. Thereafter, the mixture of body fluid and diluent is removed from the mixing chamber through the second bore of the catheter and analyzed.

Unlike the present invention which includes a mixing volume at the distal end of the dual catheter for mixing components of a multi-component sealant prior to discharge from a distal end of the catheter, the *Mammolenti '697* device fails to teach or suggest discharging any material from the distal end of the catheter. Rather, the *Mammolenti '697* device utilizes one bore of the double bore catheter to sample blood and evacuate a mixture of body fluid and diluent from the mixing chamber through the catheter body.

For at least the reasons stated above, it is respectfully submitted that independent claim 1 is not anticipated by the *Mammolenti* '697 reference.

The Redl '055 reference

Claims 1, 2, 7, and 19 were rejected as being anticipated by the *Redl* '055 reference. The *Redl* '055 reference is directed to an apparatus for applying a tissue adhesive and includes a plurality of disposable syringe bodies adapted to contain multiple components of the tissue adhesive, a connecting head attachable to the conus of the syringe bodies having separate component-conveying channels formed therein, and a gas-conveying channel attached thereto. The *Redl* '055 device may be coupled to a multiple component catheter or, in the alternative, may be coupled to a mixing needle having a plurality of mixing members positioned therein. The *Redl* '055 device fails to teach or suggest a catheter having a mixing volume, unlike the present invention which includes a mixing volume at the distal end of the dual catheter for mixing components of a multi-component sealant prior to discharge from a distal end of the catheter.

For at least the reasons stated above, it is respectfully submitted that independent claim 1 is not anticipated by the *Redl* '055 reference. Moreover, for at least the same reasons, it is submitted that dependent claims 2, 7, 19 are also patentable.

Rejections under 35 USC §103

In the Office Action dated August 8, 2002, dependent claim 5, which variously depends on independent claim 1, was rejected under 35 USC §103(a) as being obvious in view of the *Redl* '055 reference, and dependent claims 11 and 15, which variously depend on claim 1, were rejected under 35 USC §103(a) as being obvious in view of the *Hasson* '006 reference. For the reasons set forth below, the Applicants respectfully traverse the rejections and respectfully submit that the pending claims define patentable subject matter over the cited prior art.

The Redl '055 reference

The rejection of dependent claims 5 must fail for at least the same reasons as set forth in the traversal of the rejections of claims 1, 2, 7, and 19 under 35 U.S.C. §102 above. In short, the *Redl* '055 reference fails to disclose or suggest the elements of independent claims 1, and, therefore, fails as a primary reference at the outset. More

specifically, the *Redl '055* device fails to teach or suggest a catheter having a mixing volume at the distal end, unlike the present invention which includes a mixing volume at the distal end of the dual catheter for mixing components of a multi-component sealant prior to discharge from a distal end of the catheter. Thus, the cited reference does not disclose or suggest the novel features of the present invention as claimed.

For at least the reasons stated above, it is respectfully submitted that claim is not obvious in light of the *Redl '055* reference.

The Hasson '006 reference

The rejection of dependent claims 11 and 15 must fail for at least the same reasons as set forth in the traversal of the rejections of claims 1, 3, 4, and 16 under 35 U.S.C. §102 above. In short, the *Hasson '006* reference fails to disclose or suggest the elements of independent claims 1, and, therefore, fails to teach or suggest mixing fluids within the distal end of the device, unlike the presently claimed invention which mixes two fluid sealant components within the distal end of the catheter prior to dispensing the material. Thus, the cited reference does not disclose or suggest the novel features of the present invention as claimed.

For at least the reasons stated above, it is respectfully submitted that claim is not obvious in light of the *Hasson '006* reference.

CONCLUSION


For the foregoing reasons, all claims presently on file in the subject application are in condition for immediate allowance, and such action is respectfully requested.

If it is felt for any reason that direct communication with applicants' attorney would serve to advance prosecution of this case to finality, the Examiner is invited to call the undersigned attorney at the below listed telephone number.

The Commissioner is authorized to charge any fee which may be required in connection with this Amendment to deposit account No. 50-1901.

Respectfully submitted,

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

In The Claims

Please amend claims 1, 6, 9, 10, 18, and 19, and add new claims 20 and 21 as follows:

1. (Twice Amended) A multi-component sealant applicator comprising:
a dual catheter for delivering sealant; and
a mixing volume ~~[within]~~at a distal end of the dual catheter for mixing components of a multi-component sealant prior to discharge from [a] the distal end of the catheter.

6. (Amended) [An applicator according to claim 5] A multi-component sealant applicator, comprising:

a dual catheter for delivering sealant, each catheter communicating with one of a pair of fluid sealant agent sources;

a mixing volume within the dual catheter for mixing multiple components of a multi-component sealant prior to discharge from a distal end of the catheter; and

a clearing system to clear undesired material from the mixing volume or the vicinity of the mixing volume, wherein one catheter is mounted for longitudinal movement within the other and the inner catheter is usable as a plunger to remove clogs.

9. (Amended) [An applicator according to claim 2] A multi-component sealant applicator comprising:

a dual catheter for delivering sealant, each catheter communicating with one of a pair of fluid sealant agent sources;

a mixing volume within the catheter for mixing components of a multi-component sealant prior to discharge from a distal end of the catheter; and

a reciprocal drive mechanism proximally coupled with the dual catheter to move one catheter longitudinally [back and forth]with respect to the other.

10. (Amended) [An applicator according to claim 9] A multi-component sealant applicator comprising:

a dual catheter for delivering sealant, each catheter communicating with one of a pair of fluid sealant agent sources;

a mixing volume within the catheter for mixing components of a multi-component sealant prior to discharge from a distal end of the catheter; and

a reciprocal drive mechanism proximally coupled with the dual catheter to move one catheter longitudinally with respect to the other, [wherein] the drive mechanism compris[es]ing a ratchet and pawl.

18. (Amended) [An applicator according to claim 2] A multi-component sealant applicator comprising:

a dual catheter for delivering sealant, each catheter communicating with one of a pair of fluid sealant agent sources, wherein the proximal ends of the catheter are coupled to sources of sealant components, one catheter being couple[s]d through a flexible gasket allowing for relative movement of the catheters and providing a fluid seal; and

a mixing volume within the catheter for mixing components of a multi-component sealant prior to discharge from a distal end of the catheter.

19. (Amended) A method of applying a multi-component sealant through a catheter to anatomical surfaces, [that are accessible to a catheter,] comprising:

flowing multiple sealant components through a longitudinally compartmented catheter; and

mixing the components within a distal end of the catheter immediately prior to discharge.

20. (New) A multi-component sealant applicator comprising:

an inner catheter positioned coaxially within an outer catheter, the inner and outer catheters each configured for delivering one or more sealant components; and

a mixing volume at a distal end of the inner and outer catheters for mixing the one or more sealant components prior to discharge from the distal end of the inner and outer catheters.

21. (New) A multi-component sealant applicator comprising:

an inner catheter defining a first area, the inner catheter configured for delivering one or more sealant components;

an outer catheter defining a second area, the second area capable of receiving the first catheter therein and configured for delivering one or more sealant components;

a mixing volume at a distal end of the inner and outer catheters for mixing the one or more sealant components prior to discharge from the distal end of the inner and outer catheters.